



SIUD Lecture

Critical role of urodynamics in female pelvic floor dysfunctions: an update

Prof. Enrico Finazzi Agrò

Dept. of Experimental Medicine and Surgery

Tor Vergata University

UOSD Functional Urology

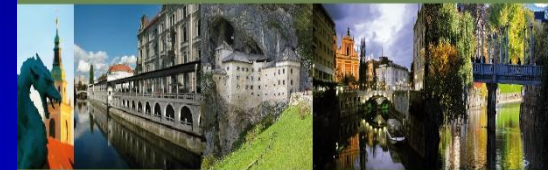
Tor Vergata University Hospital

S. Lucia Rehabilitation Hospital, IRCCS

Rome, ITALY



III Annual Meeting



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MIPS Lecture

Critical Review of the Role of Urodynamic Evaluation of Female Urinary Incontinence: Economic Implications in Mediterranean Countries

Prof. Enrico Finazzi Agrò



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Disclosures

Welcome Dr Enrico Finazzi Agro

[Profile](#) [Membership](#) [Committees](#) [Research](#) [Personal](#) [Biography](#) [Abstracts](#) [Disclosures](#)

Dr Enrico Finazzi Agro declared on the Monday 18th June 2014 that they had the following existing or known future financial relationships or affiliations:

UI* IDBATEI

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Glaxo Smith Kline

- Speaker Honorarium

Lilly

- Speaker Honorarium

Ibsa

- Speaker Honorarium

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- Consultant

Allergan

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- Speaker Honorarium

Pfizer

- Consultant
- Speaker Honorarium

Astellas

- Consultant
- Trial participation

Sigma Tau

- Consultant



ROLE OF URODYNAMICS IN INCONTINENT WOMEN

In all pts

In selected pts
(compulsory
before surgery)

In selected pts
(optional
before surgery)

Urodynamics



1980

1990

2000

2010

2015



N Engl J Med 366;21, 2012

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Trial of Urodynamic Testing before Stress-Incontinence Surgery

4083 Women with urinary incontinence
were screened for eligibility



urodynamic testing

264 Were included in the per-protocol
analysis with primary outcome data



only office evaluation

259 Were included in the per-protocol
analysis with primary outcome data



A Randomized Trial of Urodynamic Testing before Stress-Incontinence Surgery

Conclusions:

In women with uncomplicated stress urinary incontinence, a basic office evaluation as described in this report

IS A SUFFICIENT PREOPERATIVE WORKUP

Neurourology and Urodynamics 31:1118–1123 (2012)



AND

Can Preoperative Urodynamic Investigation be Omitted in Women With Stress Urinary Incontinence? A Non-Inferiority Randomized Controlled Trial

S.A.L. van Leijssen,^{1*} K.B. Kluijvers,¹ B.W.J. Mol,² S.R. Broekhuis,¹ A.L. Milani,³ M.Y. Bongers,⁴ C.I.M. Aalders,⁵ V. Dietz,⁶ G.G. A. Malmberg,⁷ M.E. Vierhout,¹ and J.P.F.A. Heesakkers⁸

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⁶Department of Obstetrics & Gynecology, Catharina Hospital, Eindhoven, The Netherlands
⁷Department of Obstetrics & Gynecology, Slingeland Hospital, Doetinchem, The Netherlands
⁸Department of Obstetrics & Gynecology, Radboud University Nijmegen Medical Centre, The Netherlands

TABLE III. Subjective and Objective Outcome According to Different Definitions of Cure

	With urodynamics, N = 31	Without urodynamics, N = 28	Relative risk [95% CI]
Primary outcome			
Mean improvement UDI-UI	34 (±22)	48 (±22)	[0.26–28] ^a
Subjective outcome			
Global improvement			
Improvement	27 (87%)	27 (96%)	0.90 [0.78–1.1]
Equal	1 (3%)	0	
Impairment	1 (3%)	1 (4%)	0.90 [0.06–14]
Missing	2 (6%)	0	
Subjective cure			
UDI, no SUI	20 (65%)	22 (79%)	0.82 [0.59–1.1]
Missing	2		
UDI-UI	16 (52%)	21 (75%)	0.69 [0.46–1.0]
Missing	2 (6%)	0	
Objective cure			
Stress test negative	25 (81%)	23 (82%)	0.98 [0.77–1.3]
Missing	4 (13%)	3 (11%)	
48-hr Voiding diary	21 (81%)	24 (86%)	0.79 [0.59–1.1]
Missing	5 (16%)	1 (4%)	
Complete cure of SUI			
Subjectively and objectively cured	17 (55%)	20 (71%)	0.77 [0.52–1.1]
Subjectively cured only	1 (3%)	0	
Objectively cured only	8 (26%)	3 (11%)	
No cure	1 (3%)	2 (7%)	0.45 [0.04–4.7]
Missing	4 (13%)	3 (11%)	

Subjective cure of SUI was defined as a no leakage reported during physical activity (UDI). Objective cure of SUI was defined as a negative stresstest by physical examination. Total cure of SUI was defined as the combination of total subjective and total objective cure. No cure was defined as objective and subjective leakage.

Number of patients; CI, confidence interval; UDI-UI, Urogential Distress Inventory subscale Urinary Incontinence.



...in uncomplicated cases...

Recommendations	GR
(NB: These refer only to neurologically intact adults with urinary incontinence)	
Clinicians carrying out urodynamics in patients with urinary incontinence should: <ul style="list-style-type: none"> • Ensure that the test replicates the patient's symptoms. • Interpret results in context of the clinical problem. • Check recordings for quality control. • Remember there may be physiological variability within the same individual. 	C
Advise patients that the results of urodynamics may be useful in discussing treatment options, <u>although there is limited evidence that performing urodynamics will alter the outcome of treatment for urinary incontinence.</u>	C
Do not routinely carry out urodynamics when offering conservative treatment for urinary incontinence.	B
<u>Perform urodynamics if the findings may change the choice of invasive treatment.</u>	B
Do not routinely carry out urethral pressure profilometry.	C

Guidelines on Urinary Incontinence

M.G. Lucas (chair), D. Bedretdinova, J.L.H.R. Bosch, F. Burkhard, F. Cruz, A.K. Nambiar, D.J.M.K. de Ridder, A. Tubaro, R.S. Pickard

Although it is routinely accepted as an option in the evaluation of an uncomplicated case of SUI, preoperative UDS can be considered to obtain additional information. Although studies have not shown improved outcomes with the addition of UDS to the preoperative evaluation, diagnoses and treatment decisions were altered in some cases.

AUA/SUFU Adult Urodynamics Guideline A Clinical Review

Clinton W. Collins, MD^a, J. Christian Winters, MD^{b,*}

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AUA/SUFU Adult Urodynamics Guideline A Clinical Review

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The Cost of Preoperative Urodynamics: A Secondary Analysis of the VALUE Trial

Peggy A. Norton,^{1*} Charles W. Nager,^{2,3} Linda Brubaker,⁴ Gary E. Lemack,⁵ Larry T. Sirls,⁶ Robert Holley,⁷
Toby C. Chai,⁸ Stephen R. Kraus,⁹ Halina Zyczynski,¹⁰ Bridget Smith,⁴ and Anne Stoddard,¹¹
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⁹*University of Texas Health Science Center, San Antonio, Texas*

¹⁰*University of Pittsburgh, Magee–Womens Research Institute, Pittsburgh, Pennsylvania*

¹¹*New England Research Institutes, Watertown, Massachusetts*

**Costs reduction if urodynamics not performed
in uncomplicated patients**



Urodynamic studies for management of urinary incontinence in children and adults: A short version Cochrane systematic review and meta-analysis

Keiran David Clement,¹ Marie Carmela M. Lapitan,^{1,2} Muhammad Imran Omar,¹
and Cathryn Margaret Anne Glazener^{3*}

¹Cochrane Incontinence Review Group, University of Aberdeen, Aberdeen, United Kingdom

²National Institutes of Health Manila, University of the Philippines Manila, Manila, Philippines

³Health Services Research Unit, University of Aberdeen, Aberdeen, United Kingdom

1.2 Number with incontinence after first year (subjective)



Fig. 2. Number of women with urinary incontinence after first year (subjective).

“...Some high-quality evidence that urodynamics do not produce lower urinary incontinence rates after treatment...”

Urodynamic studies for management of urinary incontinence in children and adults: A short version Cochrane systematic review and meta-analysis

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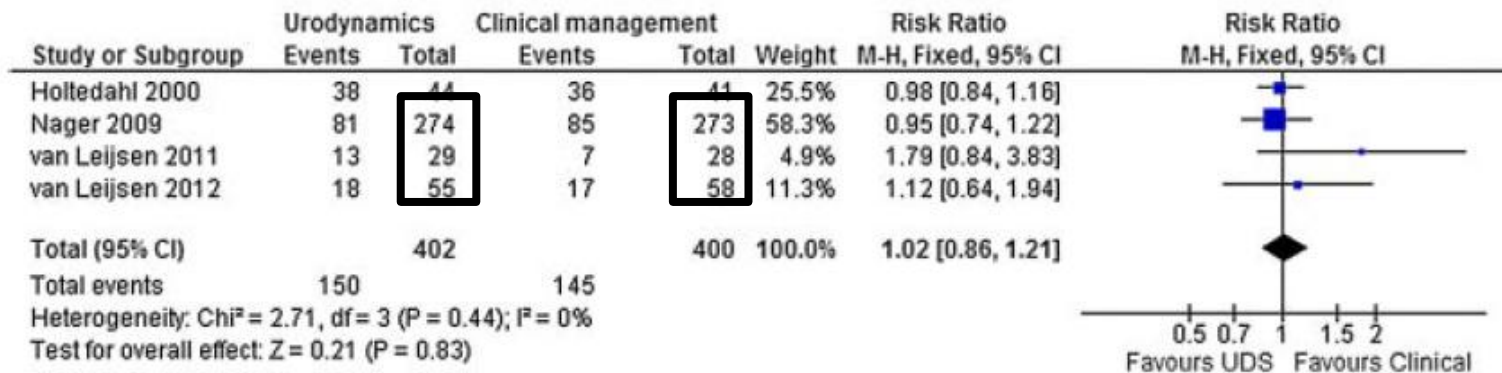


Fig. 2. Number of women with urinary incontinence after first year (subjective).

The terms “complicated” and “uncomplicated” are not present in this systematic review...



The Cost of Preoperative Urodynamics: A Secondary Analysis of the ValUE Trial

Peggy A. Norton,^{1*} Charles W. Nager,^{2,3} Linda Brubaker,⁴ Gary E. Lemack,⁵ Larry T. Sirls,⁶ Robert Holley,⁷
Toby C. Chai,⁸ Stephen R. Kraus,⁹ Halina Zyczynski,¹⁰ Bridget Smith,⁴ and Anne Stoddard,¹¹
for the Urinary Incontinence Treatment Network

“We emphasize that the ValUE data should be considered as applicable only to adult women with uncomplicated stress predominant UI planning to undergo surgery, and do not affect recommendations for UDS in the setting of complicated incontinence and voiding dysfunction”



A Randomized Trial of Urodynamic Testing before Stress-Incontinence Surgery

Inclusion criteria:

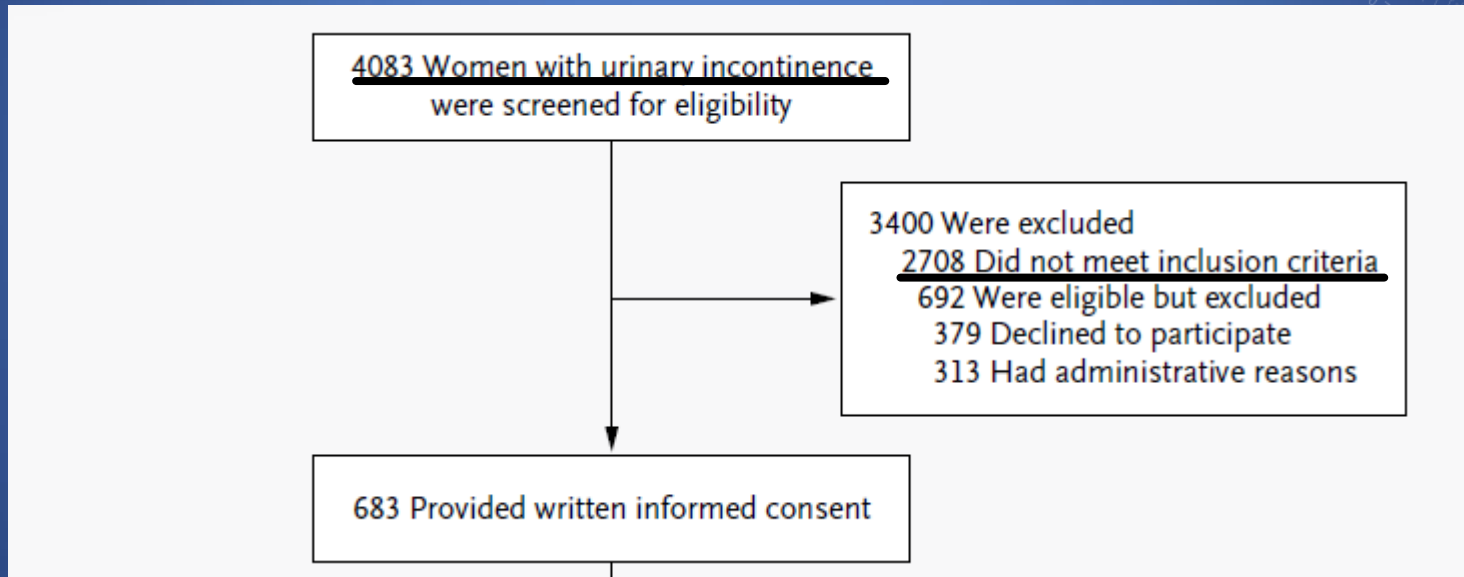
- history of symptoms of SUI for at least 3 months
- stress or mixed incontinence (if SUI prevalent)
- a post-voiding residual urine volume of less than 150 ml
- a negative urinalysis or urine culture
- a clinical assessment of urethral mobility
- a desire for surgery for SUI
- a positive provocative stress test

Exclusion criteria:

- previous surgery for incontinence
- history of pelvic irradiation
- pelvic surgery within the previous 3 months
- anterior or apical pelvic-organ prolapse of 1 cm or more distal to the hymen



A Randomized Trial of Urodynamic Testing before Stress-Incontinence Surgery



2708/4083 (66,3%): complicated patients

1375/4083 (33,7%): uncomplicated patients

Urodynamics (UDS) before surgery for female stress urinary incontinence (SUI)

Finazzi Agro E. Int Urogynecol J. 2015 Apr 30.

- VALUE trial¹: for women with uncomplicated SUI, a preoperative office evaluation is not inferior to UDS regarding 1 yr postsurgery outcomes
- Retrospective single-centre study in N=211 women having UDS prior to surgery for SUI
 - N=47 (22.3%) had uncomplicated SUI according to VALUE trial criteria
 - N=164 (77.7%) had complicated SUI according to VALUE trial criteria
- In 134/211 women (63.5%), preoperative UDS led to the diagnosis of different type of UI or diagnosis of voiding dysfunction
 - This was the case in 70.1% of complicated vs 40.4% of uncomplicated SUI cases ($P=0.0003$)
- Voiding dysfunction on UDS was observed in about 26% of cases; this could result in a worse postsurgical outcome

1) Nager CW et al. N Engl J Med 2012;366:1987-97

In this study 78% of women had complicated SUI according to VALUE criteria and UDS may give new information in 70% of these women. UDS before SUI surgery thus seems beneficial



Urodynamics Useless Before Surgery For Female Stress Urinary Incontinence: Are You Sure? Results From A Multicenter Single Nation Database

Serati Maurizio,¹ Topazio Luca,^{2*} Bogani Giorgio,¹ Costantini Elisabetta,³ Pietropaolo Amelia,⁴ Palleschi Giovanni,⁵ Carbone Antonio,⁵ Soligo Marco,⁶ Del Popolo Giulio,⁷ Li Marzi Vincenzo,⁸ Salvatore Stefano,⁹ and Finazzi Agrò Enrico¹⁰

¹Department of Obstetrics and Gynaecology, University Insubria, Varese, Italia

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⁷Spinal Unit, Careggi University Hospital, Firenze, Italia

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¹⁰Department of Experimental Medicine and Surgery, University Tor Vergata, Roma, Italia

740/2053 (36%) patients considered "uncomplicated" according to the definitions used in the VALUE trial

Uncomplicated patients are a minority

(probably around
1/3 of the patients we see)

DOI: 10.1111/1471-0528.12102



Commentary

What is the value of urodynamic studies before stress incontinence surgery?

I Giarenis, L Cardozo

Department of Urogynaecology, King's College Hospital NHS Foundation Trust, London, UK

Correspondence: Prof Linda Cardozo, Department of Urogynaecology, King's College Hospital, Denmark Hill, London, SE5 9RS, UK.

Email linda@lindacardozo.co.uk

Accepted 26 October 2012.

Accepted 26 October 2012

Email linda@lindacardozo.co.uk
Correspondence: Prof Linda Cardozo, Department of Urogynaecology, King's College Hospital, Denmark Hill, London, SE5 9RS, UK



CHOICE OF OPERATION/SURGICAL TECHNIQUE

**RPTS > TOTS IN PATIENT WITH ISD
AT 6 MONTHS AND AT 3 YEARS.**

cut-off of:

**20 cm H₂O for maximum urethral closure pressure (MUCP)
60 cm H₂O for valsalva leak point pressures (VLPP)**

Schierlitz L, et al.; Three year follow-up of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency. Obstet Gynecol 2012;



TOTS > RPTS IN PATIENT WITH VD

Richter HE, et al. Retropubic versus transobturator Midurethral slings for stress incontinence. N Engl J Med 2010;



TOTS > RPTS IN PATIENT WITH DO, URGE AND UI

*Houwert RM, et al. Risk factors for failure of retropubic and transobturator midurethral slings. Am J Obstet Gynecol 2009;
Gamble TL, et al. Predictors of persistent detrusor overactivity after transvaginal sling procedures. Am J Obstet Gynecol 2008;*



PREDICTION OF POSTOPERATIVE URGENCY, URGENCY INCONTINENCE AND VOIDING DYSFUNCTION



Low peak urinary flow rate has been identified as an independent predictor of urinary retention after RPT.

Cut-off was suggested 18 ml/s for a sensitivity of 47% and a specificity of 85%.

Hong B, et al. Factors predictive of urinary retention after a tension-free vaginal tape procedure for female stress urinary incontinence. J Urol 2003;



There are several preoperative urodynamic variables associated with persistent U/UI, such as DO, lower cystometric capacity, lower bladder volume at the first uninhibited detrusor contraction and higher opening detrusor pressure.

Jain P, et al. Effectiveness of midurethral slings in mixed urinary incontinence: systematic review and metaanalysis. Int Urogynecol J 2011;



Lee JK, et al. Persistence of urgency and urge urinary incontinence in women with mixed urinary symptoms after midurethral slings: a multivariate analysis. BJOG 2011;



Regarding de novo U and UI, pre-existing ISD and DO were independent predictors in a large retrospective study

Lee JK, et al. Which women develop urgency or urgency urinary incontinence following midurethral slings? Int Urogynecol J 2012





Urodynamics

PREDICTION OF FAILURE

The TOMUS trial showed that **lower VLPP and MUCP** were variables associated with objective **failure** 1 year after MUT on multivariate analysis.

Women with **preoperative DO** are more likely to experience treatment **failure** following MUT.

Nager CW, et al. Baseline urodynamic predictors of treatment failure 1 year after mid urethral sling surgery. J Urol 2011;

Stav K, et al. Risk factors of treatment failure of midurethral sling Procedures for women with urinary stress incontinence. Int Urogynecol J 2010;

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of UROLOGY®

International
Urogynecology
Journal

The Effect of Urodynamic Testing on Clinical Diagnosis, Treatment Plan and Outcomes in Women Undergoing Stress Urinary Incontinence Surgery

Larry T. Sirls,* Holly E. Richter,† Heather J. Litman, Kimberly Kenton, Gary E. Lemack,‡ Emily S. Lukacz,§ Stephen R. Kraus,|| Howard B. Goldman,¶ Alison Weidner,** Leslie Rickey,†† Peggy Norton, Halina M. Zyczynski‡‡ and John W. Kusek for the Urinary Incontinence Treatment Network



and John W. Kusek for the Urinary Incontinence Treatment Network
 Alison Weidner,** Leslie Rickey,†† Peggy Norton, Halina M. Zyczynski‡‡

Table 1. Clinical diagnoses after OE and UDS

Clinical Diagnosis*	No. After OE/Total No. (%)	No. After OE/No. with UDS (%)	No. After OE + UDS (%)	p Value (McNemar test)†
SUI	315/315 (100)	294/294 (100)	292/294 (99.3)	>0.99
OAB:				
Wet	131/315 (41.6)	124/294 (42.2)	74/294 (25.2)	<0.001
Dry	99/315 (31.4)	90/294 (30.6)	61/294 (20.8)	0.002
Voiding phase dysfunction	7/315 (2.2)	7/294 (2.4)	35/294 (11.9)	<0.001
Suspected ISD	61/314 (19.4)	57/293 (19.5)	36/293 (12.3)	0.003

* Patient could have more than 1 clinical diagnosis.

† Calculated in patients with UDS.

† Calculated in patients with UDS.

* Patient could have more than 1 clinical diagnosis.

NAGER CW

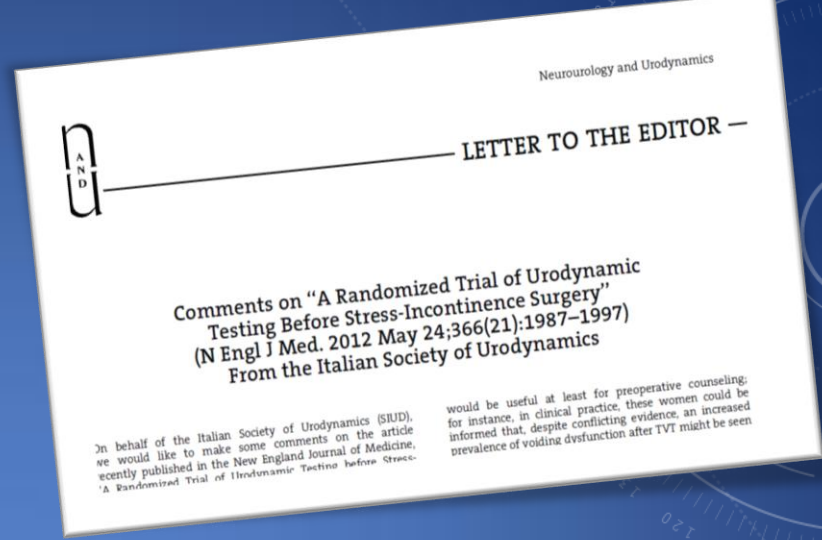
RE TO:

Voiding Dysfunction

29 vs 230 pts

62,1 vs. 78,3% success rate, $p=0,06...$

- 20% probability of success





Urodynamics Useless Before Surgery For Female Stress Urinary Incontinence: Are You Sure? Results From A Multicenter Single Nation Database

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- Voiding dysfunction
 - in **13.4%** of uncomplicated patients (similar to the **11.9%** reported in the ValUE trial)
 - In 22.5% of complicated patients

Table 2. Surgical and nonsurgical treatment plan after OE and UDS

	No. After OE/Total No. (%)	No. After OE + UDS/Total No. (%)
<i>Planned treatment</i>		
Surgical*:		
RMUS	206/315 (65.4)	192/289 (66.4)
TMUS	86/315 (27.3)	78/289 (27.0)
Mini-sling	8/315 (2.5)	7/289 (2.4)
Fascial pubovaginal sling	11/315 (3.5)	9/289 (3.1)
Retropubic urethropexy	1/315 (0.3)	0
Urethral bulking injection	3/315 (1.0)	3/289 (1.0)
Additional nonoperative treatment planned after OE:	52/315 (16.5)†	40/294 (13.6)‡
Pharmacotherapy	29/50 (58)	25/39 (64.1)
Pelvic floor therapy	27/51 (52.9)	19/39 (48.7)
Other	13/51 (25.5)	14/38 (36.8)
<i>Specific UDS driven changes to surgical plan</i>		
Surgery canceled		4/294 (1.4)
Surgical procedure changed:		16/294 (5.4)
RMUS to TMUS		8
TMUS to RMUS		5
RMUS to fascial pubovaginal sling		1
Fascial pubovaginal sling to RMUS		1
Retropubic urethropexy to RMUS		1

* Total of 315 patients had surgical treatment plan after OE, 294 had complete data after OE and UDS, and 289 had surgical treatment plan after OE and UDS (4 surgeries canceled and no data on 1).

† Total of 28 patients had additional nonoperative treatment planned after OE that was changed to no additional treatment after UDS.

‡ Total of 20 patients had UDS driven, additional nonoperative treatment plans that had not been planned after OE.

Urodynamics useless before surgery for female stress urinary incontinence: Are you sure?

Results from a multicenter single nation database

E. Finazzi Agrò¹, E. Costantini², A. Pietropaolo³, G. Palleschi⁴, A. Carbone⁴, L. Topazio⁵, M. Soligo⁶, G. Del Popolo⁷, V. Li Marzi⁸, S. Salvatore⁹, M. Serati¹⁰

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- Management strategy modified
 - in **11%** of uncomplicated patients (not far from the **6.8%** reported in the ValUE trial)
- In **23.8%** of complicated patients

AUA/SUFU Adult Urodynamics Guideline A Clinical Review

Clinton W. Collins, MD^a, J. Christian Winters, MD^{b,*}

Urol Clin N Am 41 (2014) 353–362

*“In complex, complicated patients,
preoperative UDS may be particularly helpful”*





The Cost of Preoperative Urodynamics: A Secondary Analysis of the ValUE Trial

Peggy A. Norton,^{1*} Charles W. Nager,^{2,3} Linda Brubaker,⁴ Gary E. Lemack,⁵ Larry T. Sirls,⁶ Robert Holley,⁷
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⁵*University of Texas Southwestern Medical Center, Dallas, Texas*

⁶*William Beaumont Hospital, Royal Oak, Michigan*

⁷*University of Alabama at Birmingham, Birmingham, Alabama*

⁸*Yale University, New Haven, Connecticut*

⁹*University of Texas Health Science Center, San Antonio, Texas*

¹⁰*University of Pittsburgh, Magee–Womens Research Institute, Pittsburgh, Pennsylvania*

¹¹*New England Research Institutes, Watertown, Massachusetts*

13 - 33 million dollars could be saved annually in the US



Total population of around 300.000.000

316.000.000 in the US

ECONOMICS OF URODYNAMICS IN ITALY

- Maximum reimbursement provided by Italian NHS for UDI is **206€ (223,07\$,** exchange rate of 1,082).
- A total of around **10.000** surgical procedures for female stress urinary incontinence had been performed in 2012.
- The maximum amount of money spent for UDI in these patients is consequently **2.060.000€ (2.230.700\$).**
- The percentage of “uncomplicated” patients in Italy, is 36%; therefore, UDI could have been omitted in 3.600 pts, **with a consequent saving of 741.600€ (802.441,20\$).**

Finazzi Agrò E et al, ICS 2015

ECONOMICS OF URODYNAMICS IN ITALY

- The amount of surgical procedures in Italy is **1 every 6.000 inhabitants** (Italian population: 60.000.000 people) while it's **1 every 1215 inhabitants** in the US (USA population: 316.000.000 people);
- The amount of money saved per 1.000 inhabitants is **13,72\$** in Italy, while in the US it may vary between **41,14\$** and **104,43\$**.

Finazzi Agrò E et al, ICS 2015



4 million \$ saved in Med Countries vs. 13-33 in USA

300 million € spent for pads only in Italy...

CONCLUSIONS

- Use extensively non invasive urodynamics (bladder diaries, PVR, uroflowmetry)
- Consider invasive urodynamics even in uncomplicated patients
- Use invasive urodynamics in complicated patients
 - Evaluate voiding function, assess urethral function
- Do not use invasive urodynamics without a proper indication (save costs)



Greetings from Rome!

